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510(K) SUMMARY

5.1 SUBMITTER INFORMATION

Establishment / Sponsor Name:	Invivo Corporation
Establishment / Sponsor Address:	12151 Research Parkway Orlando, FL 32826 USA
Manufacturer Name:	Philips Medical Systems
Manufacturer Address:	3000 Minuteman Road Andover, MA 01810 USA
Company Phone:	(407) 455-6166
Company Fax:	(407) 249-2022
Person to contact regarding questions:	Rusty Kelly Senior Quality & Regulatory Manager, Invivo Corporation (407) 455-6166 Rusty.Kelly@philips.com
Establishment Registration Number:	1051786 (Sponsor) 1218950 (Manufacturer)
Date Summary Prepared:	May 9, 2013

5.2 DEVICE IDENTIFICATION

Trade name:	Expression MR200 MRI Patient Monitoring System and Expression IP5 Information Portal
Common name:	MRI patient monitoring system
Classification name:	Cardiac monitor (including cardiotachometer and rate alarm) (21 CFR 870.2300, Product Code MWI)

5.3 IDENTIFICATION OF LEGALLY MARKETED CLEARED DEVICE

The Expression MR200 MRI Patient Monitoring System also referred to as the Expression MR200, and the Expression IP5 Information Portal, also referred to as the Expression IP5, are substantially equivalent to the following cleared devices:

Cleared Device	Manufacturer	510(k) No.	Clearance Date
MRI Patient Monitoring System (Model 865214)	Invivo Corporation	K090785	Dec 15, 2009
Expression Information Portal	Invivo Corporation	K121424	Jun 13, 2012

5.4 MODIFIED DEVICE DESCRIPTION

The modified device, the Expression MR200 MRI Patient Monitoring System, is predicated from the MRI Patient Monitoring System (Model 865214) that received clearance to market under 510(k) K090785 on December 15, 2009. The modified device, the Expression IP5 Information Portal is predicated from the Expression Information Portal that received clearance to market under 510(k) K121424 on June 13, 2012. The Expression IP5 is a supplement to the Expression MR200 display; together they comprise a medical system. The Expression MR200 incorporates the same indications for use and fundamental scientific technology used in the cleared device, the MRI Patient Monitoring System (Model 865214). As such, the modified Expression MR200 MRI Patient Monitoring System is substantially equivalent to the cleared device. The Expression IP5 incorporates the same indications for use and fundamental scientific technology used in the cleared device, the Expression Information Portal. As such, the Expression IP5 is substantially equivalent to the cleared device.

Invivo has marketed the cleared device, the MRI Patient Monitoring System (Model 865214), since 2009. In 2012, Invivo identified the need to market a secondary patient monitoring display as a supplement or alternate for the MRI Patient Monitoring System's display. The resultant Expression Information Portal, also referred to as the Expression IP5, was cleared to market in K121424 on June 13, 2012. The modified device, the Expression MR200 MRI Patient Monitoring System, is a lower cost alternative to the cleared MRI Patient Monitoring System (Model 865214). Therefore, the Expression IP5 is also being modified within this submission so that it may also be a supplement to the Expression MR200 MRI Patient Monitoring System display.

The cleared MRI Patient Monitoring System (Model 865214) consists of a processing unit within a Cart, a detachable wireless display, wireless ECG

module, and wireless SpO2 module. The cleared device communicates wirelessly with the Expression IP5. The Expression IP5 is a supplement or alternate for the MRI Patient Monitoring System (Model 865214) display. The Expression IP5 does not perform any data collection or processing as a stand-alone patient monitoring system. The Expression IP5 relies upon the MRI Patient Monitoring System (Model 865214) processing unit, wireless modules, and patient applied parts to complete data collection and processing. Identical to the cleared device, the Expression MR200 is capable of operating from AC mains or battery power and the wireless modules operate on battery power only. The modified device, the Expression MR200 MRI Patient Monitoring System, is structurally identical to the cleared device with the exception of the following:

- The Expression MR200 power supply is built into the Cart (rather than a separate external power converter connected to the Cart via power cord).
- The Expression MR200 display is not detachable from the Cart. Subsequently, the carrying handle has been removed from the permanent display and the transmission of information between the Cart and the MR200 display is not wireless.
- The speaker is located on the top rear of the Cart display (rather than the front of the display).
- The Alarms Setup, Printer Setup, and Monitor Setup functions are collapsed within one Setup key on the keypad which is visible to the operator at all times (rather than separate keys for each Setup function). This feature is identical to the cleared Expression IP5.
- The alarm light located on the top of the display is removed. (Other visual alarm indicators consistent with IEC 60601-1-8, error messages, and audible alarms are still provided on the modified display, identical to the cleared device. Note that the alarm light is an optional visual indication per IEC 60601-1-8.)
- A printer option is not offered in the Expression MR200 display. (The printer is provided as separate USB-connected peripheral equipment to the Expression IP5, identical to the cleared Expression IP5.)
- The NiBP and CO2 connector ports on the Expression MR200 Cart are revised slightly to accommodate the new unique connectors.
- The mechanical aesthetic design of the Cart was made consistent with other patient monitoring devices distributed by Philips Medical Systems.

The modified Expression IP5 is a supplement to the Expression MR200 display. Identical to the cleared device, the Expression IP5 operates on AC mains power only. Identical to the cleared devices, communication between the Expression MR200 and the Expression IP5 is wireless and the Expression IP5 relies upon the Expression MR200 processing unit, wireless modules, and patient applied parts to complete data collection and processing.

The cleared device provides patient monitoring data for ECG, pulse oximetry (SpO_2), respiration, non-invasive blood pressure (NiBP), invasive blood pressure (IBP), temperature, oxygen (O_2), end-tidal carbon dioxide (CO_2), and anesthetic agents. The cleared device is capable of providing the patient's pulse rate data derived from ECG, SpO_2, or NiBP. The modified device, the Expression MR200, employs the same parameters as those cleared to market in 510(k) K090785 with the exception of invasive blood pressure, temperature, oxygen, and anesthetic agents. The modified device is capable of providing the patient's pulse rate data derived from ECG or SpO_2 only; NiBP-derived pulse rate is not provided in the modified device. The cleared and modified devices are intended for the neonatal, pediatric, and adult patient populations. The cleared and modified devices provide user-adjustable alarms which are generated by the patient monitoring system display and the Expression IP5 display.

The wireless ECG module collects all ECG data, performs most of the ECG gradient filtering, and transmits the data to the processing unit within the Expression MR200 Cart. Additional ECG filtering, data processing, and heart rate derivation is performed in the Expression MR200 Cart. The modified device incorporates the same wireless ECG module, ECG processor in the Cart, and electrodes that are currently used with the cleared device. All ECG patient cables are identical to those cleared to market with the MRI Patient Monitoring System (Model 865214), with the exception of the Advanced Filter ECG Cable. The ECG leads on the Advanced Filter ECG Cable have been lengthened from 5 inches to 11 inches for improved performance during Vectorcardiography (VCG) applications when providing signals for synchronization for the MRI scanner. The cable trunk design that includes the resistance and insulation, the connector, and the electrode clips are identical to the cleared device. The modified device has the same intended use, indications for use, performance specifications, and labeling as the cleared device regarding ECG.

The cleared device's SpO_2 patient data is obtained from the wireless SpO_2 module. The wireless SpO_2 module collects and processes all SpO_2 and bellows-derived respiration data and transmits the data to the processing unit within the cleared device's Cart. Identical to the cleared device, the modified device's SpO_2 patient data is obtained from the cleared wireless SpO_2 module. The wireless SpO_2 module collects and processes all SpO_2 and bellows-derived respiration data and transmits the data to the processing unit within the modified device's Cart. The modified device incorporates the same wireless SpO_2 module, fiber optic sensor, clips, and grips that are currently used with the cleared device. Therefore, the modified device has the same intended use, indications for use, performance specifications, and labeling as the cleared device regarding SpO_2.

The cleared device's NiBP patient data is collected and measured in the processing unit within the Cart. Identical to the cleared device, NiBP data collection and measurement is performed in the modified device's processing unit within the Cart. However, in the modified device, the NiBP data collection and measurement is completed using the picoNBP OEM module that was cleared to market in 510(k) K051366 on September 14, 2005. The picoNBP OEM module is a complete non-invasive arterial blood pressure measurement unit that incorporates all hardware control and signal processing and the algorithms to derive systolic, diastolic, and mean blood pressure. The derived data is provided to the Expression MR200 MRI Patient Monitoring System.

The cleared device's CO_2 patient data is collected and measured in the processing unit within the Cart. Identical to the cleared device, inspired and end-tidal CO_2 data collection and measurement is performed in the modified device's processing unit within the Cart. However, in the modified device, the CO_2 data collection and measurement is completed using the LoFlo C5 CO_2 sensor that was cleared to market in 510(k) K053174 on January 12, 2006.

The cleared device's respiration patient data is bellows-derived from the SpO2 measurement. The modified device's respiration patient data can be bellows-derived from the SpO_2 measurement, identical to the cleared device, or derived from the CO_2 measurement.

The cleared device's processing unit transmits the patient data and power/communication status to the detachable display and the Expression IP5 using telemetry. Identical to the cleared device, the modified device's processing unit transmits the patient data and power/communication status to the Expression IP5 using telemetry. However, the modified device's processing unit transmits the patient data and power/communication status to the Expression MR200 immovable display using a wired connection. In the cleared and modified devices, all data and status transmission occurs simultaneously using a transceiver and antenna that support bi-directional 2.4 GHz wireless communication and operate within the frequency band reserved for industrial, scientific, and medical (ISM) equipment.

The cleared device's detachable display and the modified device's permanent display incorporate an LCD display for viewing, and keypad and rotary knob for navigation. When located within the MR control, induction, or recovery rooms, the cleared device's detachable display may provide data output to the Hospital Information System (HIS) in ASCII character format via connection to a third-party serial-to-Ethernet adapter wired to the RS232 port on the rear of the display. In addition, the cleared device may provide data output to the HIS in HL7 format via a standard Ethernet connection on the cleared Expression IP5. The modified

device, the Expression MR200, does not provide HIS-interface data output directly from the Expression MR200. However, the Expression MR200 may provide HIS-interface data output via the modified Expression IP5 in a manner identical to the cleared device. The cleared and modified Expression IP5s provide data output to the HIS in HL7 format, compliant to HL7 Messaging Standard Version 2.6. No data is input from the HIS to the cleared or modified devices. The cleared and modified Expression IP5 Information Portals employ a touchscreen LCD display.

The following modifications have been incorporated to create the modified devices:

- Mechanical aesthetic design of the Cart is consistent with other patient monitoring devices distributed by business lines within Philips Medical Systems. (The mechanical design of the cleared device employed a shape and color scheme consistent with Invivo devices prior to the acquisition by Philips Medical Systems.)
- The power supply for the Expression MR200 is built into the Cart (rather than a separate external power converter connected to the Cart via power cord in the cleared device).
- The display is not detachable from the Cart. Subsequently, the carrying handle has been removed from the permanent display.
- The speaker is located on the top rear of the Cart display (rather than the front of the display).
- The Alarms Setup, Printer Setup, and Monitor Setup functions are collapsed within one Setup key on the keypad which is visible to the operator at all times (rather than separate keys for each Setup function). This feature is identical to the cleared Expression IP5.
- The alarm light located on the top of the display is removed. (Other visual alarm indicators consistent with IEC 60601-1-8 and error messages are still provided identical to the cleared device. Note that the alarm light is an optional visual indication per IEC 60601-1-8.)
- A printer option is not offered in the Expression MR200 display. (The printer is provided as separate USB-connected peripheral equipment to the Expression IP5, identical to the cleared Expression IP5.)
- The NiBP and CO2 connector ports on the Expression MR200 Cart are revised slightly to accommodate the new unique connectors.
- The gauss limitation for the Cart is at or outside the 1,500 (1,500 or less) gauss (0.15T) field line of the MR system, but in no case closer than 1.5 m (4.9 feet) as measured from the center line of the MR bore. (The cleared device's gauss limitation is 5000 Gauss.)
- A gauss detection meter and alarm is included in the Cart to detect the presence of high magnetic fields and warn the user when the Cart is positioned beyond its gauss limitation.

- The ECG cable leads have been lengthened from 5 inches to 11 inches on the Advanced Filter ECG Cable that was cleared to market in 510(k) K090785 on December 15, 2009. The cable trunk design that includes the resistance and insulation, the connector, and the electrode clips are identical to the cleared device. The modified ECG cable is named the Advanced Apps ECG Cable.
- NiBP data collection and measurement is completed using the picoNBP OEM module that was cleared to market in 510(k) K051366 on September 14, 2005.
- NiBP cuffs and hoses that were validated with the picoNBP OEM module are being distributed with the Expression MR200. However, NiBP hoses were modified from a 3.0-meter length to 5.0-meter length to ensure sufficient slack when the patient is fully inserted in the MR system bore.
- CO_2 data collection and measurement is completed using the LoFlo C5 CO_2 sensor that was cleared to market in 510(k) K053174 on January 12, 2006.
- CO_2 cannula and sample line combined length was reduced from 22 feet to 17 feet as a result of a vendor modification. Identical to the cleared device, the reduced length provides sufficient slack when the patient is located within the MR system bore and the reduced length does not impact the safety or effectiveness of the CO_2 module or the modified device. In addition, the CO_2 cannula and sample line are constructed of one continuous piece terminated in a unique connector for attaching to the Expression MR200 Cart. A water trap is no longer required or employed in the modified device, as the modified device includes a filter and sample cell integrated into the cannula. (The cleared device employed a 3-piece system comprised of a water trap, sample line, and cannula. The water trap was required for the cleared device's CO_2 and anesthetic agents sampling, but is not required by the LoFlo C5 CO_2 sensor.)
- Software in the Expression IP5 permits wireless communication with the Expression MR200.

5.5 INTENDED USE

The intended use of the modified devices as described in its labeling has not changed from that of the cleared devices as a result of the modification.

The Expression MR200 MRI Patient Monitoring System and Expression IP5 Information Portal are intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner. The Expression MR200 MRI Patient Monitoring System and the Expression IP5

Information Portal are intended for use by healthcare professionals. The Expression MR200 MRI Patient Monitoring System and the Expression IP5 Information Portal provide monitoring for the following vital sign parameters: ECG, pulse oximetry (SpO_2), non-invasive blood pressure (NiBP), and optionally, carbon dioxide (CO_2).

5.6 SUMMARY OF NON-CLINICAL PERFORMANCE DATA

The performance data included in this submission establishes substantial equivalence of the modified devices, the Expression MR200 MRI Patient Monitoring System and Expression IP5 Information Portal, to the cleared devices which received market clearance in 510(k) K090785 on December 15, 2009 and 510(k) K121424 on June 13, 2012 respectively. The modified devices were evaluated to the following safety and performance guidance and tests:

- FDA Guidance Documents
- FDA performance standards
- Voluntary consensus standards
- Verification and validation of performance specifications
- Verification and validation of MR conditions of use
- Environmental testing
- Evaluation of wireless technology

In all testing, the device was verified using a worst-case environment.

FDA Guidance Documents

The modified devices, Expression MR200 MRI Patient Monitoring System and Expression IP5 Information Portal, are designed and evaluated in accordance with the following FDA Guidance Documents:

- Use of Standards in Substantial Equivalence Determinations (Issued March 12, 2000)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (Issued May 11, 2005)
- Radio-Frequency Wireless Technology in Medical Devices, Draft Guidance (Issued January 3, 2007)
- Guidance for Industry - Wireless Medical Telemetry Risks and Recommendations (Issued September 27, 2000)
- Draft Guidance for Industry and Food and Drug Administration Staff – Applying Human Factors and Usability Engineering to Optimize Medical Device Design (Issued June 22, 2011)
- Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management (Issued July 18, 2000)
- Premarket Assessment of Pediatric Medical Devices (Issued May 14, 2004)

- Guidance for Industry: Cardiac Monitor Guidance (including Cardiotachometer and Rate Alarm) (Issued November 5, 1998)
- Pulse Oximeters – Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff (Issued March 4, 2013)
- Non-Invasive Blood Pressure (NIBP) Monitor Guidance (Issued March 10, 1997)

FDA Performance Standards

The modified ECG cable was evaluated to the FDA performance standard defined in 21CFR898.12, which references compliance to subclause 56.3(c) of IEC 601-1 and its amendments. IEC 601-1 (1988) with Amendments 1 (1991) and 2 (1995) have been superseded by IEC 60601-1 (1988) with Amendments 1 (1991) and 2 (1995). Evaluation to IEC 60601-1 (1988) with Amendments 1 (1991) and 2 (1995) resulted in a determination that all of the ECG cables distributed with the Expression MR200 MRI Patient Monitoring System, including the modified ECG cable, are compliant with section 56.3(c) of IEC 60601-1 (1988) with Amendments 1 (1991) and 2 (1995).

Voluntary Standards

Standards Data Reports (Form FDA 3654 (06/11)) are provided in **Section 9** of this notification. The Expression MR200 MRI Patient Monitoring System and Expression IP5 Information Portal were evaluated to the following voluntary consensus standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety (including clause 14 for Programmable electrical medical systems and clause 16 for Medical electrical systems)
- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60601-1-6, Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Usability
- IEC 60601-1-8, Medical electrical equipment - Part 1-8: General requirements for safety - Collateral Standard: Alarm Systems - Requirements, tests and guidance - General requirements and guidelines for alarm systems in medical equipment
- IEC 60601-2-27, Medical electrical equipment – Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiograph monitoring equipment

- IEC 60601-2-33, Medical electrical equipment – Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis
- IEC 60601-2-49, Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- IEC 62366, Medical Devices – Application of usability engineering to medical devices
- IEC 80601-2-30, Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 80601-2-55, Medical electrical equipment – Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-61, Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ANSI/AAMI/ISO 10993-5, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 14971, Medical devices – Application of risk management to medical devices
- ISO 21647, Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ANSI/AAMI EC13, Cardiac monitors, heart rate meters and alarms
- ANSI/AAMI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- ANSI/AAMI SP10, Manual, electronic, or automated sphygmomanometers
- ASTM F2052-06, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- UL 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety

The modified devices, Expression MR200 MRI Patient Monitoring System and Expression IP5 Information Portal, are evaluated by a third party laboratory to

IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6 and IEC 62366, IEC 60601-1-8, IEC 60601-2-27, IEC 60601-2-49, IEC 80601-2-30, ISO 80601-2-55, ISO 80601-2-61, ANSI/AAMI ES60601-1, and UL 60601-1. The modified devices comply with the applicable requirements of these standards. The complete IEC 60601-1-2 test report is provided in **Appendix B**.

Compliance of the modified device's NiBP cuffs and cannulas to ISO 10993-1, ISO 10993-5, and ISO 10993-10 is demonstrated through third party laboratory testing. Additional evaluation of the ECG and SpO2 patient-applied parts is not required because these parts are the same parts used with the cleared device. Test reports and justification are provided in **Section 15**.

Identical to the cleared devices, compliance of the modified device to ISO 14971 is demonstrated by risk assessment provided in **Section 14**.

Compliance of the LoFlo C5 CO_2 sensor to the applicable sections of ISO 21647 is demonstrated through verification testing completed by the CO_2 module vendor and reviewed by Invivo Corporation. The LoFlo C5 CO_2 sensor complies with the applicable requirements of this standard.

Compliance of the modified device to the applicable sections of ANSI/AAMI EC13 and ANSI/AAMI SP10 is demonstrated through verification testing performed by Invivo Corporation. The modified devices comply with the applicable requirements of these standards.

Compliance of the modified devices to IEC 60601-2-33, ASTM F2503, and ASTM F2052 was demonstrated through validation testing performed by Invivo Corporation in the MR environment. The modified devices comply with the applicable requirements of these standards. Labeling is provided in **Section 12**. Test results are provided in **Appendix D**.

A Standards Summary Report Table noting deviations, adaptations, or options used in demonstrating compliance of the modified devices is provided in **Section 9**.

Verification and Validation of Performance Specifications

All performance specifications of the modified device, the Expression MR200 MRI Patient Monitoring System, were defined by Invivo Corporation according to national standards, international standards, market needs, risk management, and intended use. The verification and validation protocol for the specifications that are modified from the cleared device are provided in **Section 14**.

Results of the verification and validation indicate that the modified devices operate as intended within the performance specifications and are substantially equivalent to the cleared devices. The results do not raise issues regarding the safety and effectiveness of the devices and clinical data was not required to substantiate claims of safety and effectiveness.

Verification and Validation of MR Conditions of Use

The MR conditions of use of the modified device, the Expression MR200 MRI Patient Monitoring System, are defined by Invivo Corporation according to national standards, international standards, intended use, risk management, and market needs. Test results demonstrate that the Expression MR200 MRI Patient Monitoring System meet the MR conditions of use as defined in the modified device labeling. Details and test results are provided in **Appendix D**.

Since the MR conditions of use of the modified Expression IP5 Information Portal are unchanged from that of the cleared device as a result of this submission and the Expression IP5 is intended for use outside the MR system room only, it was not necessary to perform additional testing for the Expression IP5 MR conditions of use.

Environmental Testing

Environmental specifications for the modified device, the Expression MR200 MRI Patient Monitoring System, are defined by Invivo Corporation according to international standards, intended use, risk management, and market needs. Testing will be completed for temperature, humidity, altitude, shock, vibration, and drop per the storage and operating specifications. Test results will demonstrate conformity to customer requirement specifications over the device use life and ensure longevity of the modified device within the use model. Test data was not provided in this submission but is contained within the modified device's Design History File.

Since the environmental specifications of the modified Expression IP5 Information Portal are unchanged from that of the cleared device as a result of this submission, it was not necessary to perform additional environmental testing on the Expression IP5.

Evaluation of Wireless Technology

The radio module used in the cleared and modified devices was evaluated to FCC Part 15 for Low Power Communication Device Transmitters. Test results are summarized in **Section 14**.

The modified devices, the Expression MR200 MRI Patient Monitoring System and the Expression IP5 Information Portal, incorporate the same radio (transceiver, antenna, and performance specifications) that are currently used with the cleared devices.

Even though the radios in the modified devices are unchanged as a result of this submission, the modified Expression MR200, cleared wireless ECG module, cleared wireless SpO_2 module, and modified Expression IP5 were validated to confirm continued integrity of the wireless technology. Results indicate that the devices operate as intended. Results are provided in **Appendix C**.

Conclusion

The conclusion of all testing confirms that all identified risks have been mitigated, the device operates as designed and intended within the performance specifications and the device meets the labeling claims.

The results demonstrate that the modified devices perform as well or better than the cleared devices. The results do not raise issues regarding the safety and effectiveness of the device and clinical data was not required to substantiate claims of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 15, 2013

Invivo Corporation
c/o Mr. Rusty Kelly
Sr. Regulatory Affairs Official
12151 Research Pkwy
Orlando, FL 32826 US

Re: K131382
Trade/Device Name: Expression MR200 MRI Patient Monitoring System, Expression IP5 Information Portal
Regulation Number: 21 CFR 870.2300
Regulation Name: Physiological Patient Monitor (Without Arrhythmia Detection Or Alarms)
Regulatory Class: II (two)
Product Code: MWI
Dated: June 19, 2013
Received: June 21, 2013

Dear Mr. Rusty Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known):

Device Name: Expression MR200 MRI Patient Monitoring System (Model MR200) and Expression IP5 Information Portal (Model IP5)

Indications For Use:

The Expression MR200 MRI Patient Monitoring System (Model MR200) and the Expression IP5 Information Portal (Model IP5) are intended to monitor vital signs for patients undergoing MRI procedures and to provide signals for synchronization for the MRI scanner.

The Expression MR200 MRI Patient Monitoring System (Model MR200) and the Expression IP5 Information Portal (Model IP5) are intended for use by healthcare professionals.

The Expression MR200 MRI Patient Monitoring System (Model MR200) and the Expression IP5 Information Portal (Model IP5) provide monitoring for the following vital sign parameters: ECG, pulse oximetry (SpO2), non-invasive blood pressure (NIBP), and optionally, carbon dioxide (CO2).

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen A. Faris -S
Date: 2013.07.15 11:31:08 -04'00'